

SETTLEMENT AGREEMENT

This Settlement Agreement ("Agreement") is entered into among the United States of America, acting through the United States Department of Justice and on behalf of the Office of Inspector General of the Department of Health and Human Services, and Dr. Joseph Shehadi (hereafter collectively referred to as "the Parties"), through their authorized representatives.

RECITALS

A. Dr. Joseph Shehadi ("Dr. Shehadi") is a neurosurgeon practicing in Columbus, Ohio. Dr. Shehadi is the sole member and manager of Joseph A. Shehadi, M.D., Neurosurgery Associates, LLC, an Ohio limited liability company.

B. SpineFrontier, Inc. ("SpineFrontier") is a corporation with an office in Malden, Massachusetts. At all times relevant to this agreement, Dr. Kingsley R. Chin owned 98.6% of SpineFrontier through KICVentures, LLC and other affiliated companies that he wholly owned. At all relevant times, SpineFrontier developed, manufactured, distributed, marketed, and sold medical devices used during spine surgeries.

C. Impartial Medical Experts, LLC ("IME") is a Florida-based legal entity that Dr. Kingsley R. Chin wholly owned through KICVentures, LLC and other affiliated companies that he wholly owned. At all relevant times, IME's "Business Administrator" and sole employee was Vanessa J. Dudley, Chin's wife.

D. The United States contends that Dr. Shehadi submitted or caused to be submitted claims for payment to the Medicare Program, Title XVIII of the Social Security Act, 42 U.S.C. §§ 1395-1395lll ("Medicare" a "Federal Health Care Program").

E. The Anti-Kickback Statute, 42 U.S.C. § 1320a-7b ("AKS"), prohibits the payment or receipt of remuneration to induce or reward the purchase of an item or service for

which payment is made in whole or in part under a Federal Health Care Program, including Medicare. A claim that includes items or services resulting from a violation of the AKS constitutes a false or fraudulent claim for purposes of the False Claims Act, 31 U.S.C. § 3730 *et seq.*

F. The United States contends that it has certain civil claims against Dr. Shehadi for submitting or causing the submission of false claims to Medicare that resulted from violations of the AKS, in connection with the conduct described in Paragraph G below.

G. Dr. Shehadi admits, acknowledges, and accepts his responsibility for the following facts:

1. Shortly after Dr. Shehadi first learned of SpineFrontier from a colleague in early 2014, IME invited Dr. Shehadi to become a consultant ostensibly to provide feedback on the design and usability of SpineFrontier products. On or about June 1, 2014, Dr. Shehadi entered into a consulting agreement with IME, pursuant to which SpineFrontier, via IME, agreed to pay Dr. Shehadi at a rate of \$500 per hour. Dr. Shehadi did not perform any purported consulting services for any company other than SpineFrontier pursuant to the IME agreement.
2. Between June 1, 2014 and December 31, 2015, SpineFrontier paid Dr. Shehadi, through IME, a total of \$61,037.50 in purported consulting fees. During this time, Dr. Shehadi utilized SpineFrontier products, including in surgical procedures reimbursed by Medicare.
3. Dr. Shehadi reported consulting hours to SpineFrontier materially in excess of the number of hours he actually spent engaged in consultative activities, and SpineFrontier paid Dr. Shehadi for consulting hours he did not work. Dr. Shehadi did so in part based on guidelines SpineFrontier, through its officer, Aditya Humad, communicated to him, namely that Dr. Shehadi could bill a flat rate of 1 to 1.5 hours whenever he used one of SpineFrontier's cervical spine products, and a flat rate of 2 hours whenever he used one of SpineFrontier's lumbar spine products, ostensibly for "evaluations" of those products. SpineFrontier paid Dr. Shehadi consulting fees even when Dr. Shehadi provided no substantive feedback to SpineFrontier whatsoever, or provided only minimal feedback.
4. At certain times, Spinefrontier did not pay Dr. Shehadi for the full amount of the hours he submitted via IME. In response to Dr. Shehadi's inquiries, SpineFrontier, via Mr. Humad, told him that he did not use enough of SpineFrontier's products to justify his consulting hours. Mr. Humad further communicated that, if Dr. Shehadi

used more SpineFrontier products, then SpineFrontier could pay him more "consulting" fees.

5. SpineFrontier did not communicate to Dr. Shehadi that his purported consulting work was unsatisfactory, even when SpineFrontier paid Dr. Shehadi for product evaluations with minimal or no substantive content.

The conduct described in this Paragraph G shall hereinafter be referred to as the "Covered Conduct."

In consideration of the mutual promises and obligations of this Settlement Agreement, the Parties agree and covenant as follows:

TERMS AND CONDITIONS

1. Dr. Shehadi shall pay to the United States \$323,419.50, plus interest at a rate of 2.00% per annum from January 23, 2020 through the day before full payment (the "Settlement Amount"), no later than 30 days after the Effective Date of this Agreement by electronic funds transfer pursuant to written instructions to be provided by the Office of the United States Attorney for the District of Massachusetts. Of the Settlement Amount, \$161,709.75 is restitution to the United States.

2. Subject to the exceptions in Paragraph 3 (concerning excluded claims) below, and conditioned upon Dr. Shehadi's full payment of the Settlement Amount, the United States releases Dr. Shehadi from any civil or administrative monetary claim the United States has for the Covered Conduct under the False Claims Act, 31 U.S.C. §§ 3729-33; the Civil Monetary Penalties Law, 42 U.S.C. § 1320a-7a; the Program Fraud Civil Remedies Act, 31 U.S.C. §§ 3801-12; or the common law theories of payment by mistake, unjust enrichment, and fraud.

3. Notwithstanding the release given in Paragraph 2 of this Agreement, or any other term of this Agreement, the following claims of the United States are specifically reserved and are not released:

- a. Any liability arising under Title 26, U.S. Code (Internal Revenue Code);
- b. Any criminal liability;
- c. Except as explicitly stated in this Agreement, any administrative liability, including mandatory or permissive exclusion from Federal health care programs;
- d. Any liability to the United States (or its agencies) for any conduct other than the Covered Conduct;
- e. Any liability based upon obligations created by this Agreement;
- f. Any liability of individuals other than Dr. Shehadi;
- g. Any liability for failure to deliver goods or services due; and
- h. Any liability for personal injury or property damage or for other consequential damages arising from the Covered Conduct.

4. Dr. Shehadi waives and shall not assert any defenses Dr. Shehadi may have to any criminal prosecution or administrative action relating to the Covered Conduct that may be based in whole or in part on a contention that, under the Double Jeopardy Clause in the Fifth Amendment of the Constitution, or under the Excessive Fines Clause in the Eighth Amendment of the Constitution, this Agreement bars a remedy sought in such criminal prosecution or administrative action.

5. Dr. Shehadi fully and finally releases the United States, its agencies, officers, agents, employees, and servants, from any claims (including attorney's fees, costs, and expenses of every kind and however denominated) that Dr. Shehadi has asserted, could have asserted, or may assert in the future against the United States, and its agencies, officers, agents, employees,

and servants related to the Covered Conduct and the United States' investigation and prosecution thereof.

6. The Settlement Amount shall not be decreased as a result of the denial of claims for payment now being withheld from payment by any Medicare contractor (e.g., Medicare Administrative Contractor, fiscal intermediary, carrier), TRICARE, the VA, or any state payer, related to the Covered Conduct; and Dr. Shehadi agrees not to resubmit to any Medicare contractor, TRICARE, the VA, or any state payer any previously denied claims related to the Covered Conduct, agrees not to appeal any such denials of claims; and agrees to withdraw any such pending appeals.

7. Dr. Shehadi agrees to the following:

a. Unallowable Costs Defined: All costs (as defined in the Federal Acquisition Regulation, 48 C.F.R. § 31.205-47; and in Titles XVIII and XIX of the Social Security Act, 42 U.S.C. §§ 1395-1395III-1 and 1396-1396w-5; and the regulations and official program directives promulgated thereunder) incurred by or on behalf of Dr. Shehadi, his employees, and his agents in connection with:

- (1) the matters covered by this Agreement;
- (2) the United States' audit(s) and civil and any criminal investigation(s) of the matters covered by this Agreement;
- (3) Dr. Shehadi's investigation, defense, and corrective actions undertaken in response to the United States' audit(s) and civil and any criminal investigation(s) in connection with the matters covered by this Agreement (including attorney's fees);
- (4) the negotiation and performance of this Agreement; and

- (5) the payment Dr. Shehadi makes to the United States pursuant to this Agreement

are unallowable costs for government contracting purposes and under the Medicare Program, Medicaid Program, TRICARE Program, and Federal Employees Health Benefits Program (FEHBP) (hereinafter referred to as Unallowable Costs).

b. Future Treatment of Unallowable Costs: Unallowable Costs shall be separately determined and accounted for by Dr. Shehadi, and Dr. Shehadi shall not charge such Unallowable Costs directly or indirectly to any contracts with the United States or any State Medicaid program, or seek payment for such Unallowable Costs through any cost report, cost statement, information statement, or payment request submitted by Dr. Shehadi or any of its subsidiaries or affiliates to the Medicare, Medicaid, TRICARE, or FEHBP Programs.

c. Treatment of Unallowable Costs Previously Submitted for Payment: Dr. Shehadi further agrees that within 90 days of the Effective Date of this Agreement he shall identify to applicable Medicare and TRICARE fiscal intermediaries, carriers, and/or contractors, and Medicaid and FEHBP fiscal agents, any Unallowable Costs (as defined in this Paragraph) included in payments previously sought from the United States, or any State Medicaid program, including, but not limited to, payments sought in any cost reports, cost statements, information reports, or payment requests already submitted by Dr. Shehadi or any of its employees or agents, and shall request, and agree, that such cost reports, cost statements, information reports, or payment requests, even if already settled, be adjusted to account for the effect of the inclusion of the unallowable costs. Dr. Shehadi agrees that the United States, at a minimum, shall be entitled to recoup from Dr. Shehadi any overpayment plus applicable interest and penalties as a result of

the inclusion of such Unallowable Costs on previously-submitted cost reports, information reports, cost statements, or requests for payment.

Any payments due after the adjustments have been made shall be paid to the United States pursuant to the direction of the Department of Justice and/or the affected agencies. The United States reserves its rights to disagree with any calculations submitted by Dr. Shehadi on the effect of inclusion of Unallowable Costs (as defined in this Paragraph) on Dr. Shehadi's cost reports, cost statements, or information reports.

d. Nothing in this Agreement shall constitute a waiver of the rights of the United States to audit, examine, or re-examine Dr. Shehadi's books and records to determine that no Unallowable Costs have been claimed in accordance with the provisions of this Paragraph.

8. Dr. Shehadi agrees to cooperate fully and truthfully with the United States' investigation of individuals and entities not released in this Agreement.

9. This Agreement is intended to be for the benefit of the Parties only. The Parties do not release any claims against any other person or entity, except to the extent provided for in Paragraph 10 (waiver for beneficiaries paragraph), below.

10. Dr. Shehadi agrees that he waives and shall not seek payment for any of the health care billings covered by this Agreement from any health care beneficiaries or their parents, sponsors, legally responsible individuals, or third party payors based upon the claims defined as Covered Conduct.

11. Each Party shall bear its own legal and other costs incurred in connection with this matter, including the preparation and performance of this Agreement.

12. Each party and signatory to this Agreement represents that it freely and voluntarily enters in to this Agreement without any degree of duress or compulsion.

13. This Agreement is governed by the laws of the United States. The exclusive jurisdiction and venue for any dispute relating to this Agreement is the United States District Court for the District of Massachusetts. For purposes of construing this Agreement, this Agreement shall be deemed to have been drafted by all Parties to this Agreement and shall not, therefore, be construed against any Party for that reason in any subsequent dispute.

14. This Agreement constitutes the complete agreement between the Parties. This Agreement may not be amended except by written consent of the Parties.

15. The undersigned counsel represent and warrant that they are fully authorized to execute this Agreement on behalf of the persons and entities indicated below.

16. This Agreement may be executed in counterparts, each of which constitutes an original and all of which constitute one and the same Agreement.


17. This Agreement is binding on Dr. Shehadi's successors, transferees, heirs, and assigns.

18. All parties consent to the United States' disclosure of this Agreement, and information about this Agreement, to the public.


19. This Agreement is effective on the date of signature of the last signatory to the Agreement (Effective Date of this Agreement). Facsimiles and electronic transmissions of signatures shall constitute acceptable, binding signatures for purposes of this Agreement.

THE UNITED STATES OF AMERICA

DATED: 3/5/2020

BY: 
ABRAHAM GEORGE
DAVID J. DERUSHA
Assistant United States Attorneys
United States Attorney's Office
District of Massachusetts

DATED: 01/31/2020

BY: 
LISA M. RE
Assistant Inspector General for Legal Affairs
Office of Counsel to the Inspector General
Office of Inspector General
United States Department of Health and Human Services

DR. JOSEPH SHEHADI - DEFENDANT

DATED: 01/30/2020 BY: *Joseph Shehadi MD*
DR. JOSEPH SHEHADI

1/30/20

D. Michael Crites

DATED: 1/30/20 BY: *Daniel Zinsmaster* by DMCrites per authorization
D. MICHAEL CRITES
DANIEL ZINSMASER
Dinsmore & Shohl LLP
Counsel for Dr. Joseph Shehadi